

Biotech Daily

Wednesday April 22, 2009

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP; LIVING CELL UP 13%, SUNSHINE HEART DOWN 6%
- * BIONOMICS: BNC105 'VERY EFFECTIVE' FOR THROAT CANCER
- * PROGEN INVESTORS OVERWHELMINGLY BACK BUY-BACK
- * CIRCADIAN LICENCED ANTIBODY BOOSTS CHEMOTHERAPY IN MICE
- * PHYLOGICA RAISES \$3.8m
- * NEUREN CANCER COMPANY HALTS SHARE RISE
- * COMPUMEDICS WINS \$500k+ US SLEEP DIAGNOSTICS ORDERS
- * CHINESE PATENT FOR PRIMA'S CANCER ANTIBODY TREATMENT
- * VIRALYTICS OPTION RIGHTS ISSUE TO RAISE \$3m; \$12m IN CONVERSION
- * MEDICAL THERAPIES REJECTS 'TROJAN' INVESTORS
- * STARPHARMA SHARE PLAN TO RAISE POSSIBLE \$2.2m
- * BIOTA PLEADS SCHULTZ, ROYALTIES TO ASX 31% PRICE QUERY
- * AVEXA APPOINTS EX-GILEAD JOE BAINI DIRECTOR
- * CEPHALON TAKES 31% OF ARANA

MARKET REPORT

The Australian stock market slipped 0.25 percent on Wednesday April 22, 2009 with the S&P ASX 200 down 9.2 points to 3,668.2 points. Thirteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and eight were untraded.

Living Cell was best, up 3.5 cents or 25 percent to 17.5 cents with 119,000 shares traded followed by Bionomics up 19.1 percent to 25 cents and Viralytics up 11.4 percent to 3.9 cents. Circadian climbed 9.3 percent; Tyrian was up 8.7 percent; Avexa and Clinuvel climbed more than six percent; Pharmaxis was up 5.6 percent; Genera, Impedimed and Sirtex put on more than three percent; with Cellestis and Phosphagenics up more than two percent. Prima and Neuren again had strong volume sales (see below.)

Sunshine Heart led the falls, down 0.5 cents or 6.25 percent to 7.5 cents with 77,000 shares traded, followed by Alchemia and Phylogica down more than five percent. Acrux and Optiscan fell more than four percent; Benitec, Chemgenex and Novogen were down more than three percent; Mesoblast and Resmed shed more than two percent; with Cochlear and CSL down more than one percent.

BIONOMICS

Bionomics says preclinical data confirms its anti-cancer compound BNC105 is "a very effective anti-cancer agent in a model of human throat cancer".

In a presentation to the American Association for Cancer Research Conference in Denver, Colorado, Bionomics said BNC105 had been shown to be "very effective in shutting down the blood supply to tumors in mouse models of human breast, prostate, lung, colon, brain, head and neck cancers".

Bionomics said tumors of the throat belonged to the class of head and neck cancers and included a group of biologically similar cancers of the lip, mouth, nose, and throat.

"These cancers are often diagnosed at an advanced stage and current treatment options are surgical resection, radiation and chemotherapy," the company said.

Bionomics said the data demonstrated that BNC105 had dual anti-cancer activities, killing cancer cells directly as well as shutting down the blood supply of advanced tumors of the throat.

The company said a single cycle of BNC105 treatment was "very effective in delaying the growth of throat tumors in animal models and improving the survival rate of the animals". The data also showed that BNC105 "effectively combines with radiation therapy to yield a

more effective anti-tumor response against this cancer type [and] appears to ameliorate radiation induced tumor ulceration".

Bionomics' chief executive officer Dr Deborah Rathjen said the potential of BNC105 for the treatment of head and neck cancers could be "an attractive option for patients since they are often diagnosed only after the disease has reached an advanced stage".

"Head and neck cancers account for approximately three to five percent of all cancers in the United States whilst in Australia head and neck cancers are the eighth most common cancer," Dr Rathjen said.

"These cancers are more common in men and in people over age 50 and risk factors include smoking and alcohol consumption," Dr Rathjen said.

The company said that data on the effectiveness of BNC105, both as a single agent and in combination with the cytotoxic agent cisplatin, in treating lung cancer in animal models was also presented at the conference.

Bionomics said BNC105 suppressed the growth of lung tumors and effectively combined with cisplatin to give enhanced anti-tumor effect and prolong survival.

The company said the two main types of lung cancer were small cell lung cancer and nonsmall cell lung cancer.

In the US up to 200,000 patients are diagnosed with lung cancer each year, Bionomics said.

Bionomics said BNC105 was in a US Food and Drug Administration approved phase I clinical trial in patients with advanced cancers at four Melbourne hospitals: the Peter MacCallum Cancer Centre, the Western Hospital, the Austin Hospital and the Royal Melbourne Hospital.

A copy of the AACR presentation is at: <u>www.bionomics.com.au</u>. Bionomics was up four cents or 19.05 percent to 25 cents.

PROGEN

Progen shareholders have overwhelmingly supported the \$1.10 share buy-back capped at \$40 million (BD: Mar 10, 2009).

A resolution put to the extraordinary general meeting was passed with 25,447,872 proxy votes in favor and 151,451 proxy votes against.

Progen was untraded at 85 cents.

CIRCADIAN TECHNOLOGIES

Circadian says Eli Lilly scientists have shown that its antibody to vascular endothelial growth factor receptor 3 inhibits mouse-model tumors, with standard chemotherapy. Circadian managing director Robert Klupacs told Biotech Daily that his company owned the intellectual property to the vascular endothelial growth factor receptor 3 and the right to make antibodies to it and had licenced the right to make the antibodies to Eli Lilly's wholly-owned subsidiary, Imclone Systems.

Circadian said Imclone had shown in preclinical mouse studies that a monoclonal antibody targeting the vascular endothelial growth factor receptor 3 (VEGFR-3) protein combined effectively with standard chemotherapy treatments to inhibit the growth of tumors in subcutaneous mouse tumor models.

Circadian said the data was presented at the American Association for Cancer Research conference demonstrating that the combination of a VEGFR-3 antibody with the standard anti-cancer chemotherapy agents for lung cancer, cisplatin, or for head and neck cancer, docetaxel, gave significantly better results in tumor inhibition than either agent alone as demonstrated in subcutaneous mouse tumor models.

The presentation was entitled 'Potentiation of cytotoxic therapy in subcutaneous xenograft models with an antagonist monoclonal antibody to VEGFR-3'.

Mr Klupacs said the data showed VEGFR-3 antibodies "may have the potential to improve existing chemotherapy treatments".

"We believe that this data supports the potential of VEGFR-3 antibodies as a novel and promising cancer treatment," Mr Klupacs said.

In October 2008 Imclone Systems and Circadian said the VEGFR-3 antibody, IMC-3C5, had been designated as a formal pre-clinical development candidate for oncology indications.

Circadian said IMC-3C5 was an antibody which inhibited VEGFR-3.

The company said peer-reviewed publications had shown that VEGFR-3 played "an important role in the development of blood vessels and lymphatic vessels supporting tumors".

Blocking the VEGFR-3 pathway might have the potential to block tumor growth and metastasis by starving tumors of blood supply and preventing the spread of cancerous cells through the lymphatic system, the company said.

Imclone is developing IMC-3C5 under an exclusive license from Circadian through a wholly owned subsidiary in return for annual licence fees and royalties on potential future product sales.

As well as the Imclone product being developed, Circadian had a three pre-clinical drugs VGX-100, VGX-200 and VGX-300, two of which were antibody drugs.

Circadian was up seven cents or 9.3 percent to 82 cents.

PHYLOGICA

Phylogica has raised \$3.84 million through a placement at five cents to new and existing investors along with a further placement and the issue of convertible notes.

Phylogica said the shareholder-approved and oversubscribed placement raised \$1.2 million at five cents a share and a further \$1.4 million worth of shares was placed to investors.

Phylogica deputy chairman Harry Karelis told Biotech Daily that directors acquired \$1.04 million in two-year, non-redeemable, no coupon notes converting to shares at five cents or at maturity at four cents along with a \$200,000 of notes to an unrelated party. Phylogica fell 0.4 cents or 5.7 percent to 6.6 cents.

NEUREN PHARMACEUTICALS

Neuren and the New Zealand-based Breast Cancer Research Trust have established a company to target breast and other cancers based on Neuren's intellectual property rights. Neuren's share price fell on the announcement following several days of dramatic share price rises on larger than usual volumes (BD: Apr 21, 2009).

Headquartered in Auckland, Perseis Therapeutics will focus on developing Neuren's TFF-1, TFF-3 and anti-growth hormone programs.

The Breast Cancer Research Trust will provide \$NZ1.18 million (\$A932,000) in funding to obtain definitive in vivo proof of efficacy for all three programs .

Neuren said that at the end of the first round of funding, Perseis would seek additional funding, licencing or co-development agreements to continue development of the programs.

The company said the TFF-1 program had been licenced to a European specialty pharmaceutical company and Neuren re-acquired rights to the program at no cost, while the other company has taken an option to licence the program back by March 2010. Neuren shareholders will retain a majority interest in Perseis with remaining shares held by the Breast Cancer Research Trust.

Neuren chairman Dr Robin Congreve said antibody-based therapeutics for cancer were "a large and growing market and include several of the biggest selling cancer drugs".

"Already we have received significant interest in funding or licensing these technologies at the in vivo proof of concept stage," Dr Congreve said.

"Validating the targets and approach with this first tranche of funding in partnership with the Breast Cancer Research Trust enables us to retain significantly more value for Neuren shareholders than would traditional venture financing or early stage licencing," he said. "For cancer patients, the technology offers promising therapeutic potential and we are excited about being able to develop the technologies for these patients," Dr Congreve said.

Neuren said therapeutic products that specifically target molecules involved in cancer progression and spread, known as molecularly targeted cancer therapies, were increasingly recognized as the future of cancer therapy.

The company said that for breast cancer, these include Herceptin and Tamoxifen, which target the HER2 and oestrogen receptors, respectively.

Neuren said many breast cancers neither expressed the oestrogen receptor nor were HER2 positive and therefore were not responsive to the therapies that target them.

The company said the Perseis cancer program targeted the trefoil factors (TFF-1 and TFF-3) and growth hormone which played a significant role in the growth and spread of breast cancer and response to treatment and offered "promising targets for development of therapies for cancers which are not responsive to currently available drugs".

In vitro and in vivo studies have demonstrated strongly positive effects of antibodies directed against these molecules in breast and other cancers, Neuren said.

Neuren fell 2.7 cents or 38.03 percent to 4.4 cents with 26.7 million shares traded.

MEDICAL THERAPIES

Medical Therapies says it has scaled back its \$700,000 placement of shares at one cent a share fearing some investors may want to take control of the company.

Medical Therapies chief executive officer Maria Halasz told Biotech Daily the placement had been scaled back to \$340,000 following "concerns over some investments".

The new shares come with one free attaching option for every five new shares acquired. Medical Therapies was untraded at two cents.

COMPUMEDICS

Compumedics says it has won orders worth "more than \$500,000" for sleep-diagnostic equipment sales in its key US market in the first months of 2009.

Compumedics executive chairman David Burton said he could not disclose the precise number or value of the orders but said they came in rapid succession at a time of significant economic distress in the US.

Compumedics told the ASX each order was worth about \$285,000.

The company said the hospitals and medical institutions which placed the orders "demand quality, technical innovation and reliability and, as such, Compumedics is a natural vendor of choice".

"Importantly, some of these deals displaced equipment provided initially by existing competitors, which confirms Compumedics' technological lead in its range of sleepdiagnostic equipment," the company said.

Compumedics fell half a cent or 3.45 percent to 14 cents.

PRIMA BIOMED

Prima says its subsidiary company, Oncomab, has received notification of grant from the Chinese Patent Office for its cancer antibody antigen Cripto-1.

Prima said Cripto-1 was a protein found in high levels on the surface of many different kinds of cancer cells and was also found in the blood stream of cancer patients.

The company said the antibody worked by binding to the Cripto-1 molecule and interfering with cell signaling, which resulted in the death of the cancer cell.

Prima said the antibody might additionally be coupled to cytotoxic drugs "to deliver an even more lethal combination of drug and cell signal to cancer cells".

The patent is entitled 'Antibodies against cancer' and expires in March 2021 and has been granted in Australia, New Zealand and the US.

Prima is in negotiations to secure a major pharmaceutical co-development partner to commercialize Cripto-1.

Prima climbed 1.4 cents or 21.9 percent to 7.8 cents with 163.6 million shares traded.

VIRALYTICS

Viralytics hopes to raise up to \$3.0 million through the issue of one one cent option for each share held and a further \$12.1 million if all options are converted to shares. Viralytics managing director Bryan Dulhunty told Biotech Daily that a rights issue for options was unusual for the ASSX, let alone the biotechnology sector, but had previously occurred in mining companies several years ago.

Mr Dulhunty said the options converted to shares at four cents, meaning that the share price only needed to increase to more than five cents a share to make the exercise worthwhile for investors.

He said the option rights issue would "give shareholders more upside" than, say, a twofor-six rights issue and had the potential to raise funds for the company as it reached its milestones.

Mr Dulhunty said Viralytics expected to complete its three phase I trials by June 2010 and hoped to be ready to start a phase II trial in Australia and the US by the end of 2010. The company is offering up to 302,138,460 options in the rights issue.

The record date for eligible shareholders is May 5, 2009.

The offer opens on May 8 and closes on May 27, 2009.

Viralytics was up 0.4 cents or 11.43 percent to 3.9 cents.

STARPHARMA

Starpharma is offering shareholders up to \$10,000 worth of shares at 26 cents a share. A Starpharma executive told Biotech Daily the company did not disclose how much it expected to raise but expected about 10 percent of its 2,200 shareholders would apply for shares in line with "current market experience".

Along with its recent \$4.3million to \$4.6 million placement (BD: Apr 7, 2009), Starpharma said that the share plan would support development activities to commercialize the Vivagel coated condom with SSL International Plc; supplement funding to advance the stand-alone Vivagel development program; support partnering and commercialization of its dendrimer applications; and strengthen the balance sheet with additional working capital. The company said shareholders at the record date of April 7, 2009 would be eligible to participate in the plan.

The non-renounceable offer opens on April 23 and closes on May 6, 2009.

Parcels of shares can be bought in a range from \$1,000 to \$10,000.

The offer is not underwritten.

Starpharma was unchanged at 30 cents.

BIOTA

Biota has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 65 cents on April 17, 2009 to 85 cents, a 30.8 percent increase, on April 21, 2009, along with an increase in trading volume. Biota said that Glaxosmithkline had indicated its intention to announce Relenza sales to March 31, 2009 at noon British Summer Time on April 22, 2009.

Biota will provide a concurrent ASX announcement on indicative Relenza royalties with the Glaxosmithkline release, recognizing the difference in business hours, but prior to 10am on April 23, 2009.

Biota did not mention recent board changes as a reason for the increased share price (BD: Nov 28, 2008; Mar 2, 2009).

Biota fell half a cent or 0.64 percent to 78 cents.

<u>AVEXA</u>

Avexa has appointed former Gilead executive Joe Baini as a non-executive director. Avexa said Mr Joe Baini had more than 20 years experience in the "commercialization, marketing and sales of top selling drugs".

Prior to founding consulting company Exec Factor in 2008, Mr Baini was the general manager of Gilead Sciences Australia, New Zealand and Asia.

Avexa said at Gilead for five years, he led the team which launched Viread, "achieving the fastest market share uptake in Australian HIV history".

Mr. Baini's team also launched Hepsera for hepatitis B and Truvada for HIV.

Prior to Gilead, Mr Baini was marketing director for Bayer Australia where he realigned the organization enabling the re-launch of two drugs.

Mr Baini has held management positions at Pharmacia & Upjohn and Merck Sharpe and Dohme and is a director of the Bio-Melbourne Network.

Mr Baini has a Bachelor of Science in pharmacology and biochemistry from the University of Melbourne and has completed coursework in marketing, product management and leadership.

Avexa climbed 0.6 cent or 6.6 percent to 9.7 cents.

<u>ARANA</u>

Cephalon International Holdings increased its substantial shareholding in Arana from 67,785,560 shares (29.78%) to 71,169,711 shares (31.26%) to on April 17, 2009. The change was through an increase in takeover acceptances (BD: Feb 27, Mar 2, 2009). Arana fell half a cent or 0.36 percent to \$1.38.